## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

## ARTICLE DETAILS

| | |
|---|---|
| **TITLE (PROVISIONAL)** | The effect of spinal orthoses and postural taping on balance, gait and quality of life in older people with thoracic hyperkyphosis: Protocol for a systematic review and meta-analysis |
| **AUTHORS** | aboutorabi, atefeh<br>Ahmadi Bani, Monireh<br>Arazpour, Mokhtar<br>Keshtkar, Abbasali |

## VERSION 1 - REVIEW

| | |
|---|---|
| **REVIEWER** | Wendy Katzman |
| **REVIEW RETURNED** | 28-Jan-2017 |

| | |
|---|---|
| **GENERAL COMMENTS** | This manuscript is a protocol for a systematic review and meta-analysis to investigate the effect of spinal orthoses and postural taping on balance, gait and quality of life in older people with thoracic hyperkyphosis. The authors present their proposed methods including search strategy, data extraction, quality assessment, publication bias and data synthesis.<br><br>There are a few things that I would like to point out and questions that need to be addressed.<br>1. Page 2, line 45: It would be useful to state clearly the general outcomes that you will be investigating in the article summary. As it states now, I don't think it is correct to say "for the first time" because there have been previous reviews of the efficacy of spinal orthoses and taping in older adults .<br>2. The background does not discuss what is known and not known about spinal orthoses and postural taping on balance, gait and quality of life in older people with thoracic hyperkyphosis. There have been previous systematic reviews synthesizing the evidence of effectiveness of spinal orthoses and taping for adults with vertebral osteoporosis on outcomes including balance and gait (Newman, 2015; Goodwin, 2016; Barker, 2015), and these should be also discussed in the background given that many people with hyperkyphosis have vertebral fractures.<br>3. Are you searching for studies that use orthoses AND bracing, or orthoses AND/OR bracing. Please clarify.<br>4. Page 4, line 16: In the introduction, you mention pharmacologic therapy for the management of hyperkyphosis but to my knowledge there is no evidience to support this. Furthermore, these interventions listed do not optimize BMD. If otherwise, please cite references.<br>5. In the interventions section, again please clarify whether studies with orthoses AND bracing, or orthoses AND/OR bracing will be included.<br>6. Page 4, line 31: Strengthen the case for the need for this |

| | |
|---|---|
| | review by also stating that other studies report no significant differences, thus the need for your review.<br>7. Page 11, line 35: please change the verbiage as “if the bias in not ignorable is not grammatically correct.<br>8. Page 11, line 48: the reference to sample size is not clear.<br>9. Page 12, line 24: consider changing to “determine the effectiveness or utility of orthotic interventions” rather than to choose. |

| | |
|---|---|
| **REVIEWER** | Professor Karen Barker |
| **REVIEW RETURNED** | 3-Mar-2017 |

| | |
|---|---|
| **GENERAL COMMENTS** | Overall this is well written and of interest.<br>Two very similar reviews have been completed and published recently which are not referenced - Goodwin V - BMJ Open 2016, Newman M Arch Phys Med Rehab 2015.<br><br>Measures of kyphosis vary and within the source articles the definition of kyphosis and hyperkyphosis will differ, need to be clear in protocol what definitions of kyphosis and hyperkyphosis are being used. This needs further consideration - potentially link range of motion to age<br><br>Not clear if orthoses used after acute osteoporotic vertebral fracture to prevent spinal deformity and hyperkyphosis are included<br><br>The quality assessment is described but no consideration appears to be given to whether a formal meta-analysis is appropriate - i.e. the authors appear to assume that it will be.<br>However, the literature in this area shows considerable heterogeneity in terms of population, intervention, orthosestype, outcome measures used including timing of measures and QUALITY<br>Given this it is debatable whether further statistical analysis is possible - this should be acknowledged and the authors should specifically consider this and how they will analyse if meta-analysis not feasible. |

| | |
|---|---|
| **REVIEWER** | Slavko Rogan |
| **REVIEW RETURNED** | 11-Mar-2017 |

| | |
|---|---|
| **GENERAL COMMENTS** | This protocol deals with a very interesting topic. Some weakness of this protocol could be found.<br><br>Major revision<br><br>May attention of the referencing style. Now and then there is a gap between word and referencing.<br><br>Introduction<br><br>1. The introduction described the theoretical background of postural taping not enough. This should explain more in detail.<br>2. Furthermore, the first two paragraphs should be deleted, because these parts are not relevant for this review. |

| | |
|---|---|
| | Objectives<br>1. Formulate one research question<br>2. Formulate only one primary outcome not three: balance, gait and quality of life only one outcome<br><br>Methods<br><br>Type of participants: why include older participants at least of 50 years? The definition of the WHO is 55 years of age … use this one<br><br>Interventions: I'm understand the intervention as follows you will include studies which compare spinal orthoses + the weighted kypho-orthosis (WKO), TLSOs, TLOs and LSOs) + postural taping (= these three components all together) against inactive control or other co-interventions.<br>The question that arise is, how could you decide the effectiveness of spinal orthoses alone or tape alone or weighted kypho-orthosis alone. This combining is inadequate this not allow a clear statemant I suggest combining and writing more clearly for readers as<br>1) spinal orthoses + postural taping,<br>2) the weighted kypho-orthosis + postural taping against inactive control or only spinal orthoses alone or the weighted kypho-orthosis alone.<br><br>Outcomes<br>Please define only one primary outcome |

**VERSION 1 – AUTHOR RESPONSE**

Reviewers' Comments to Author:
Reviewer 1: Reviewer Name: Wendy Katzman Institution and Country: University of California San Francisco, USA Competing Interests: None declared

This manuscript is a protocol for a systematic review and meta-analysis to investigate the effect of spinal orthoses and postural taping on balance, gait and quality of life in older people with thoracic hyperkyphosis. The authors present their proposed methods including search strategy, data extraction, quality assessment, publication bias and data synthesis.

There are a few things that I would like to point out and questions that need to be addressed.
1. Page 2, line 45: It would be useful to state clearly the general outcomes that you will be investigating in the article summary. As it states now, I don't think it is correct to say "for the first time" because there have been previous reviews of the efficacy of spinal orthoses and taping in older adults .
Reply 1: you are certainly right. We added general outcome measures "balance" to the mentioned line and we deleted "for the first time" according to your suggestion. Thanks for kind consideration.

2. The background does not discuss what is known and not known about spinal orthoses and postural taping on balance, gait and quality of life in older people with thoracic hyperkyphosis. There have been previous systematic reviews synthesizing the evidence of effectiveness of spinal orthoses and taping for adults with vertebral osteoporosis on outcomes including balance and gait (Newman, 2015; Goodwin, 2016; Barker, 2015), and these should be also discussed in the background given that many people with hyperkyphosis have vertebral fractures.
Reply2: thank you for scientific and valuable comment, we revised the last paragraph of background has been rewritten as below:
"The use of spinal orthoses and postural taping is one alternative form of conservative treatment. These orthoses help in improving balance and preventing falls as well as correcting posture, Pfeifer et al. showed that the use of the Spinomed orthosis resulted in a decrease in centre of mass (COM) sway and subsequently improved balance in older women. However, Current evidence surrounding

spinal orthoses is inconsistent. Many people with hyperkyphosis have vertebral fractures. There have been previous systematic reviews synthesizing the evidence of effectiveness of spinal orthoses and taping for osteoporotic adults with vertebral fractures. However, vertebral fractures do not comprise all cases of hyperkyphosis. About one third of the older persons with hyperkyphosis have underlying vertebral fractures. Previous reviews conducted a broad search strategy in this area, indicating unclear risk of bias and inconsistent results between studies. Additionally, due to non-reporting of significant differences in these reviews, quantitative syndethesis (meta-analysis) was not conducted. Therefore, the aim of this review is to combine evidence about the efficacy of spinal orthoses/bracing and taping on balance of elderly with hyperkyphosis and assessing and finding of source of heterogeneity between studies."

3. Are you searching for studies that use orthoses AND bracing, or orthoses AND/OR bracing. Please clarify.
Reply3: we are searching for studies that use orthoses OR Brace. This was corrected in background and objectives with green coloured text in manuscript. Furthermore, we also added "bracing" in keywords syntax. This was explained completely in PubMed search strategy in supplementary file.

4. Page 4, line 16: In the introduction, you mention pharmacologic therapy for the management of hyperkyphosis but to my knowledge there is no evidience to support this. Furthermore, these interventions listed do not optimize BMD. If otherwise, please cite references.
Reply 4: thank you for constructive comment. Clinical guidelines for the non-operative management of age-related hyperkyphosis do not currently exist. Potential modalities include exercise-based interventions, spinal orthoses and postural taping to optimize body alignment and kyphosis angle. We are certainly consistent with you and we corrected these sentences to avoid misunderstanding as below:

"Non-surgical management of age-related hyperkyphosis includes exercise-based interventions, spinal orthoses and postural taping to optimize body alignment and improvement in thoracic kyphosis"

5. In the interventions section, again please clarify whether studies with orthoses AND bracing, or orthoses AND/OR bracing will be included.
Reply 5: thank you for diligent reviewing. We revised intervention & comparison section as below:
"We will include studies which compare spinal orthoses (such as the Spinomed, Osteo-med, Posture Training Support (PTS), the weighted kypho-orthosis (WKO), TLSOs, TLOs and LSOs) OR bracing OR postural taping with inactive control, as well as studies that involve other co-interventions (for example exercise) provided the co-interventions are applied in the same manner to both the control and experimental group participants. For non-controlled studies, only those where the evaluation related to the spinal orthoses OR bracing OR taping will be included. We will exclude spinal orthoses that are part of functional electrical stimulation treatment."

6. Page 4, line 31: Strengthen the case for the need for this review by also stating that other studies report no significant differences, thus the need for your review.
Reply 6: thank you for helpful comment, your suggestion was added to the last paragraph of introduction.

7. Page 11, line 35: please change the verbiage as "if the bias in not ignorable is not grammatically correct.
Reply 7: thanks for your watchful comment; we corrected the sentence as below
"If bias is non-ignorable, we will use …"

8. Page 11, line 48: the reference to sample size is not clear.
Reply 8: thanks for your precision. Our mean must be stated clearly. For calculating effect size measure, we will use outcome variable mean and standard deviation and sample size each group to calculate SMD (standardized mean difference). To clarify, we revised text as below:

"Then, the data required for calculating the effect-size measure will be collated in a 2 by 2 table, using the outcome variable mean and standard deviation (SD) and sample size in two intervention and comparison/control groups"

9. Page 12, line 24: consider changing to “determine the effectiveness or utility of orthotic interventions” rather than to choose.
Reply 9: this change was considered in manuscript. Thank you for suggestion.

Dear Wendy Katzman, Thank you for your letter and constructive comments concerning our manuscript

Reviewer: 2 Reviewer Name: Professor Karen Barker Institution and Country: Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, University of Oxford, Oxford, UK Competing Interests: None declared Overall this is well written and of interest.

1)Two very similar reviews have been completed and published recently which are not referenced - Goodwin V - BMJ Open 2016, Newman M Arch Phys Med Rehab 2015.
Reply1: Thank you very much for this insightful comment, which was also referenced by Reviewer 1; we discuss these studies in background to strengthening our review. These studies were referenced in background with green highlighted text as below
“The use of spinal orthoses and postural taping is one alternative form of conservative treatment. These orthoses help in improving balance and preventing falls as well as correcting posture, Pfeifer et al. showed that the use of the Spinomed orthosis resulted in a decrease in centre of mass (COM) sway and subsequently improved balance in older women. However, Current evidence surrounding spinal orthoses is inconsistent. Many people with hyperkyphosis have vertebral fractures. There have been previous systematic reviews synthesizing the evidence of effectiveness of spinal orthoses and taping for osteoporotic adults with vertebral fractures. However, vertebral fractures do not comprise all cases of hyperkyphosis. About one third of the older persons with hyperkyphosis have underlying vertebral fractures. Previous reviews conducted a broad search strategy in this area, indicating unclear risk of bias and inconsistent results between studies. Additionally, due to non-reporting of significant differences in these reviews, quantitative syndethesis (meta-analysis) was not conducted. Therefore, the aim of this review is to combine evidence about the efficacy of spinal orthoses/bracing and taping on balance of elderly with hyperkyphosis and assessing and finding of source of heterogeneity between studies.”

2) Measures of kyphosis vary and within the source articles the definition of kyphosis and hyperkyphosis will differ, need to be clear in protocol what definitions of kyphosis and hyperkyphosis are being used. This needs further consideration - potentially link range of motion to age
Reply 2: Thank you for your constructive comment,
About kyphosis measurement, as you stated, there are different techniques such as radiography (measuring Cobb angle) or such devices as the kyphometer, goniometer, inclinometer, and flexible ruler. Our manuscript as a secondary research will include all studies that used all of these techniques.
About definition, there is not uniformly accepted thresholds for defining either hyperkyphosis but according to most of documents we will include studies which kyphosis angle was considered greater than 45 degree. These mentioned items were added to manuscript with yellow colour.

3) Not clear if orthoses used after acute osteoporotic vertebral fracture to prevent spinal deformity and hyperkyphosis are included
Reply 3: thank you, we will include those studies with hyperkyphosis because of osteoporosis with or without vertebral compression fracture, disk degeneration; poor spinal muscles strength and soft tissue degeneration in acute and chronic conditions.
However, we will classify different condition by sub-group meta-analysis.

4) The quality assessment is described but no consideration appears to be given to whether a formal meta-analysis is appropriate - i.e. the authors appear to assume that it will be.
However, the literature in this area shows considerable heterogeneity in terms of population, intervention, orthosestype, outcome measures used including timing of measures and QUALITY
Given this it is debatable whether further statistical analysis is possible - this should be acknowledged and the authors should specifically consider this and how they will analyse if meta-analysis not feasible.
Reply 4: this comment is very admirable. We will try to conduct a comprehensive search including gray literature to maximize relevant studies and we will perform meta-analysis in each outcome measure will be possible. For investigating potential sources of heterogeneity, we will use a sub-group

analysis or meta-regression (this method is less restrictive in the number of small primary studies). But in severe methodological heterogeneity that meta-analysis is not possible; we will use meta-synthesis or narrative synthesis.

Dear Professor Karen Barker, we appreciate all of your insightful comments. We worked hard to be responsive to them. Thank you for taking the time and energy to help us improve the paper

Reviewer: 3 Reviewer Name: Slavko Rogan
Institution and Country: Bern University of Applied Sciences, Health, Discipline Physiotherapy, Switzerland, And Competing Interests: none declared

This protocol deals with a very interesting topic. Some weakness of this protocol could be found.

Major revision

1) May attention of the referencing style. Now and then there is a gap between word and referencing.
Reply 1: thank you for kind consideration to our work, referencing style has been checked and corrected by authors in overall manuscript.

Introduction

2) The introduction described the theoretical background of postural taping not enough. This should explain more in detail.
Reply 2: thanks for your helpful comment; we added more details about postural taping in background by gray colour as below:
“Like spinal orthoses, postural taping aims to decrease thoracic hyperkyphosis, reduce pain, and assist activity of the postural muscles in a more optimal spinal position.”

3) Furthermore, the first two paragraphs should be deleted, because these parts are not relevant for this review.
Reply 3: thank you for your comment, the first two paragraphs deleted.

Objectives
4) Formulate one research question
Reply 4: many thanks for your comment; our primary objective is the efficacy of spinal orthoses/bracing and postural taping on balance parameters

5) Formulate only one primary outcome not three: balance, gait and quality of life only one outcome
reply5: according to your comment our primary outcome was corrected as below text:
“The aim of this review is to combine evidence about the efficacy of spinal orthoses/bracing and taping on balance of elderly with hyperkyphosis and also assessing and finding of source of heterogeneity between studies.”

Methods

6) Type of participants: why include older participants at least of 50 years? The definition of the WHO is 55 years of age … use this one
Reply 6: we used it due to some definition of older subjects in Africa at least 50 years. However, your comment is valuable and we changed cut off for elderly subject to 55 years in manuscript.

7) Interventions: I’m understand the intervention as follows you will include studies which compare spinal orthoses + the weighted kypho-orthosis (WKO), TLSOs, TLOs and LSOs) + postural taping (= these three components all together) against inactive control or other co-interventions.
The question that arise is, how could you decide the effectiveness of spinal orthoses alone or tape alone or weighted kypho-orthosis alone. This combining is inadequate this not allow a clear statemant I suggest combining and writing more clearly for readers as
1) spinal orthoses + postural taping,
2) the weighted kypho-orthosis + postural taping against inactive control or only spinal orthoses alone or the weighted kypho-orthosis alone.

Reply 7: thank you for your watchful comment and suggestion.
Indeed, we will include studies that used any types of orthoses OR brace OR tape. For avoid of misunderstanding we corrected the text as below:
“ We will include studies which compare spinal orthoses (such as the Spinomed, Osteo-med, Posture Training Support (PTS), the weighted kypho-orthosis (WKO), TLSOs, TLOs and LSOs) OR bracing OR postural taping with inactive control, as well as studies that involve other co-interventions (for example exercise) provided the co-interventions are applied in the same manner to both the control and experimental group participants. For non-controlled studies, only those where the evaluation related to the spinal orthoses OR bracing OR taping will be included. We will exclude spinal orthoses that are part of functional electrical stimulation treatment.”

Outcomes
8) Please define only one primary outcome
Reply 8: thank you for your comment, as your previous comment we changed the manuscript as below:
“The primary outcomes of interest will comprise balance parameters ( CoP or CoG sway measurement) or clinically tests related dynamic balance measurement( Berg Balance Test, Functional Reach Test)”
Dear Slavko Rogan, We appreciate you taking the time to offer us your comments and insights related to the manuscript.

**VERSION 2 – REVIEW**

| | |
|---|---|
| **REVIEWER** | Wendy Katzman |
| **REVIEW RETURNED** | 13-Apr-2017 |

| | |
|---|---|
| **GENERAL COMMENTS** | I accept with very minor changes that do not require additional review.<br><br>1. Please reference your statement that exercise-based treatments are effective on page 3 line 35.<br><br>2. Page 3, line 46, change current to a lower case "c".<br><br>3. Populations 55 years and older are not considered "elderly" and this should be changed to something more accurate (ie:older) on page 4, line 9.<br><br>4. Page 5, line 21 -- change "whom" to "when" . Also, flexicurve may not produce an angular value. Depending upon manuscripts found, you could include those with flexible ruler measurements of kyphosis index >13 which is the cutpoint for hyperkyphosis. |

| | |
|---|---|
| **REVIEWER** | Karen Barker |
| **REVIEW RETURNED** | 06-Apr-2017 |

| | |
|---|---|
| **GENERAL COMMENTS** | Still needs careful proof reading and attention to quality of English that is used |

| | |
|---|---|
| **REVIEWER** | Slavk Rogan |
| **REVIEW RETURNED** | 09-Apr-2017 |

| | |
|---|---|
| **GENERAL COMMENTS** | Congratulation this manuscript improves well. This manuscript is after minor corrections acceptable for acceptance. |

| | |
|---|---|
| | My little notes are:<br><br>Page 3. Line 53&54: adjust front size<br>Page 5. Line 12. Change after randomization from comma to dot.<br>Reference:<br>The font looks different to the text. |

**VERSION 2 – AUTHOR RESPONSE**

Reviewer: 1
Reviewer Name: Wendy Katzman
Institution and Country: University of California San Francisco, USA
Competing Interests: None declared

I accept with very minor changes that do not require additional review.
1. Please reference your statement that exercise-based treatments are effective on page 3 line 35.
Reply1: thank you for your comment, Reference was added to the text.
2. Page 3, line 46, change current to a lower case "c".
Reply2: thanks, it was corrected.
3. Populations 55 years and older are not considered "elderly" and this should be changed to something more accurate (ie:older) on page 4, line 9.
Reply 3: it was corrected, thank you for your comment.
4. Page 5, line 21 -- change "whom" to "when" . Also, flexicurve may not produce an angular value. Depending upon manuscripts found, you could include those with flexible ruler measurements of kyphosis index >13 which is the cutpoint for hyperkyphosis.
Reply4: thank you for valuable comment. The cutpoint >13 was added to the manuscript.

Reviewer: 2
Reviewer Name: Karen Barker
Institution and Country: Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Scence, University of Oxford, UK
Competing Interests: None declared

Still needs careful proof reading and attention to quality of English that is used
Reply: it was rechecked and we requested Mr. John Head for revising quality of English that we used.
Reviewer: 3
Reviewer Name: Slavk Rogan
Institution and Country: Bern University of Applied Sciences, Department Health, Discipline Physiotherapy, Bern, Switzerland
Competing Interests: None declared

Congratulation this manuscript improves well. This manuscript is after minor corrections acceptable for acceptance.
My little notes are:
Page 3. Line 53&54: adjust font size
Reply1: it was corrected.
Page 5. Line 12. Change after randomization from comma to dot.
Reply 2: it was done.
Reference:
The font looks different to the text.
Reply 3: thanks so much. It was corrected consistent with the text.